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INSIDE

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New Contraceptive Ring Option Receives FDA Approval

21 days in, seven days out, for full year of contraceptive effectiveness

Get ready to add a new vaginal contraceptive ring to the currently available birth control options in the United States. Annovera, a soft, reusable, flexible silicone ring containing segesterone acetate and ethinyl estradiol, has been approved by the U.S. Food and Drug Administration (FDA).

The ring measures 2 ¼ inches in diameter and is indicated for pregnancy prevention for up to one year. Women can insert and remove the ring by themselves. They leave the device in place for 21 days and then remove it for seven days during each cycle. Developed by the Population Council, Annovera has been licensed to TherapeuticsMD. The company anticipates that the ring will be available commercially in the third quarter of 2019, with launch later that year.

> THE RING MEASURES 2 1/4 INCHES IN DIAMETER AND IS INDICATED FOR PREGNANCY PREVENTION FOR UP TO ONE YEAR.

As part of its licensing agreement with the Population Council, TherapeuticsMD will provide significantly reduced pricing for the device to family planning clinics with federal Title X designation that serve lower-income women.

"This approval is a key first step toward introducing this product globally and better meeting the sexual and reproductive health needs of women, men and young people in the U.S. and around the world," said **Jim Sailer**, executive director of the Center

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for Biomedical Research at the Population Council. "We are grateful to the dozens of researchers who have worked on this product, the donors who have funded its development, and most of all, to the thousands of women who volunteered to participate in clinical trials and made this all possible."

Anita Nelson, MD, professor and chair of the obstetrics and gynecology department at Western University of Health Sciences, says she is "delighted" that a new option is available for women who want more choice, convenience, and control in family planning.

"The Population Council has been a leader in creatively and collectively addressing women's contraceptive needs," said Nelson, a principal investigator of the Phase 3 trials, in a statement. "It is exciting they are continuing to help empower women with another contraceptive choice."

Research Backs Efficacy

Each ring contains 103 mg of segesterone acetate and 17.4 mg ethinyl estradiol, which releases on average 0.15 mg/day of segesterone acetate and 0.013 mg/day of ethinyl estradiol.

In awarding approval to the device, the FDA reviewed the results of 17 clinical trials, which included two Phase 3 trials for safety and efficacy. The advanced trials involved 2,308 women at 27 study sites in the United States, Latin America, Europe, and Australia. Study participants included healthy women ages 18 to 40 years who were instructed to use the device for 13 menstrual cycles, or one year. Based on the results of the research, approximately two to four women out of 100 may become pregnant during the first year of use.

The device carries a boxed warning regarding cigarette smoking and serious cardiovascular events. Women older than 35 years of age who smoke should not use Annovera, according to the package labeling.

The Annovera ring should not be used by women who have:

- A high risk of arterial or venous thrombotic diseases;
- Current or history of breast cancer or other estrogen- or progestin-sensitive cancer;
- Liver tumors, acute hepatitis, or severe (decompensated) cirrhosis;
- Undiagnosed abnormal uterine bleeding;
- Hypersensitivity to any of the components of the device; or
- Use of hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir.

The side effects of the new ring are similar to those of other combination hormonal birth control methods. These include headache/migraine, nausea/vomiting, yeast infections, abdominal pain, dysmenorrhea, breast tenderness, irregular bleeding, diarrhea, and genital itching.

Postmarketing studies will be conducted to evaluate the risks of venous thromboembolism associated with device use, as well as to examine the effects of CYP3A-modulating drugs and tampon use on the device's pharmacokinetics.

Will New Method Be Accepted?

According to the approved package labeling, Annovera is to remain in the vagina continuously for 21 days, and then is removed for a one-week dose-free interval. Counsel women that withdrawal bleeding usually occurs during this time. Clinicians

EXECUTIVE SUMMARY

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- Each ring contains 103 mg of segesterone acetate and 17.4 mg ethinyl estradiol, which releases on average 0.15 mg/day of segesterone acetate and 0.013 mg/day of ethinyl estradiol.

should instruct users to clean the ring with mild soap and warm water, pat it dry with a clean cloth towel or paper towel, and place it in its case during the dose-free interval. At the end of the dose-free interval, the ring should be cleaned prior to being placed back in the vagina for another 21 continuous-day cycle.

In acceptability research, 89% of women gave Annovera high marks for convenience, ease of use, and satisfaction with the device.[1]

Women may insert the ring either lying down, squatting, or standing. A woman inserts the ring by pressing the sides of the device together for insertion into the vagina. When the device is inserted properly, the vaginal system should be entirely in the vagina and behind the pelvic bone. Instruct women to note the day and time of insertion so that they may remove the ring three weeks later at approximately the same time and on the same day. A woman can remove the device by hooking an index finger into the ring inside the vagina, and gently pulling out the device.

The efficacy of the contraceptive ring depends on correct, consistent use. During a 28-day cycle, if a deviation causes the ring to be out of the vagina for less than seven days, pregnancy risk will not increase. However, if a deviation leads to the ring being out for more than seven days, pregnancy risk is increased and backup contraception is recommended.

How to Use the Device

A woman who wishes to use Annovera who has not used hormonal contraceptives or had a copper intrauterine device removed in the previous menstrual cycle may initiate device use during days two through five of her menstrual cycle. No backup contraception is needed. If a woman has irregular menstrual cycles or if the start is more than five days from the last menstrual bleeding, an additional barrier method of birth control, such as a male condom or spermicide, should be used during coitus for the first seven days.

THE SIDE EFFECTS ARE SIMILAR TO THOSE OF OTHER COMBINATION HORMONAL BIRTH CONTROL METHODS.

How about women switching from combined hormonal contraception? Use of Annovera may be initiated on any day of the method's cycle (day 1-28) without the need for backup contraception. However, no more than seven hormone-free days should occur before starting Annovera.

Women who previously have used progestin-only methods, such as the contraceptive shot, implant, pill, or intrauterine device, may use Annovera if they have no contraindications to ethinyl estradiol. For patients switching from progestin-only pills, Annovera should be initiated at the time of the next pill. For those switching from an injection, the ring should be initiated at the time of the next scheduled injection. If moving from an implant or a progestin-only intrauterine device, Annovera should be started at the time of implant or device removal. In all such cases, an additional barrier method, such as a male condom or spermicide, should be used during coitus for the first seven days of ring use.

In new mothers, Annovera should not be started earlier than four weeks after childbirth, and only in those women who choose not to breastfeed. When device use is initiated four weeks or more postpartum, women should use an additional contraception method, such as male condoms or spermicide, during coitus for the first seven days if no period has yet been recorded. For new mothers who choose to breastfeed, Annovera should not be used until weaning. ■

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Company to Halt U.S. Sales of Essure Device

International pharmaceutical company Bayer has announced that it will cease U.S. sales of its Essure sterilization device as of December 2018. Although the company is halting distribution because of declining sales, the decision comes amid mounting concerns surrounding its use.

In a press statement, the company said that it will continue to stand behind Essure's safety and efficacy, providing ongoing support services through its consumer and healthcare provider websites, Essure.com and EssureMD.com, and its customer call center, 1-888-84-BAYER.

"The health and safety of the patients who rely on our products is our top priority," reads the statement. "Most importantly, we want to let the many women who have chosen Essure for their reproductive health know that our decision to discontinue sales is for business reasons, and not for any safety or efficacy concerns about Essure."

Approved for use in 2002, the Essure form of permanent birth control is made up of an implantable insert and a placement delivery system. In contrast to other permanent sterilization procedures, the device involves using a hysteroscope to place inserts into the fallopian tubes through the cervix. When the device is in place, a local reaction is elicited by fibers within the insert. This reaction causes fibrous tissue to grow in and around the implant, which then blocks the fallopian tubes. Three months after placement, it is recommended that patients undergo hysterosalpingography or ultrasound to confirm proper placement of the insert and fallopian tube obstruction. Unlike other forms of female sterilization, Essure does not require incisions, abdominal entry, or general anesthesia, and the insert can be placed in a medical office setting.[1]

Regulatory Monitoring to Continue

In 2015, the Food and Drug Administration's (FDA) Medical Devices Advisory Committee's Obstetrics and Gynecology Devices Panel convened a day-long meeting to gather scientific and clinical expert opinions on Essure, in addition to reports from women who had used the device. The meeting was conducted to evaluate the evidence after complaints about the sterilization option. Following the meeting, the FDA ordered Bayer to conduct a postmarket study to evaluate Essure's safety profile when used in the real world. Updated labeling for Essure was issued in 2016, along with a boxed warning and a patient decision checklist.

In April 2018, the agency asked for changes to the checklist, which calls for clinicians to go over the document with prospective patients to ensure their understanding of the risk and benefit information about the use of Essure. The changes called for the patient to sign an acknowledgment of risks, and for the physician responsible for device insertion to sign the checklist. Sales and distribution of the device were limited to those physicians who followed the terms of the checklist. (Contraceptive Technology Update *reported on the change; see the July 2018 article, "FDA Issues Restrictions for Sterilization Option," available at https://bit.ly/2M7m6Sg.*)

According to a statement issued by FDA Commissioner **Scott Gottlieb**, MD, the postmarket safety of Essure will continue to be a top priority for the agency.

"The agency is committed to continuing to provide updates on our evaluation of this data as the information is collected and we develop new findings about the device," said Gottlieb in the statement.

Review Other Options

Sterilization remains the most popular contraceptive option. Results from the 2006-2010 National Survey of Family Growth show that of the 38.4 million women ages 15-44 who use contraception, 47.3% of married couples rely on sterilization (tubal occlusion, 30.2%; vasectomy, 17.1%).[2] In the

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- The company says that it will continue to stand behind Essure's safety and efficacy, providing ongoing support services through its consumer and healthcare provider websites and its customer call center.
- Unlike other forms of female sterilization, Essure requires no incisions, abdominal entry, or general anesthesia, and it can be implanted in office-based settings.

United States, most tubal occlusion procedures are performed during the early postpartum period. Data indicate that sterilization procedures are performed after 8-9% of all hospital deliveries.[3]

Sterilization using the laparoscopic approach is performed for interval and postabortal tubal occlusion procedures. Providers may perform sterilization as an outpatient procedure using electrocoagulation, mechanical devices, or tubal excision. Mechanical devices include a silicone rubber band, a spring-loaded clip, and a titanium clip lined with silicone rubber.[4]

Women who have completed their childbearing are candidates for sterilization. Providers who offer sterilization should be sure to provide comprehensive preoperative counseling that includes discussions about the surgical techniques, safety and effectiveness of the procedure, potential complications, and sterilization alternatives, such as long-acting reversible contraception methods and vasectomy.[4] Data indicate that women younger than 30 years of age at the time of sterilization have high levels of regret after sterilization and are almost two times as likely to report regret as older women.[5] ■

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Options Considered for Access to Medication Abortion

Just-published research provides insight about why women choose online access to medication abortion.[1]

Researchers at the University of Texas at Austin LBJ School of Public Affairs conducted anonymous interviews with 32 people from 20 states who sought abortion medications online. Through the interviews, scientists found that those seeking medication abortion drugs online choose to do so because of barriers to clinic access in states with and without restrictive abortion laws. The choice also can happen when women prefer to self-manage their abortion rather than receive clinical care.[1]

EXECUTIVE SUMMARY

As restrictions of clinic access to abortion mount, some women may seek internet access to services. Research indicates that women seeking medication abortion drugs online choose to do so because of barriers to clinic access in states with and without restrictive abortion laws. The choice also can happen when women prefer to self-manage their abortion rather than receive clinical care.

• For some abortion providers, telemedicine has offered a chance to extend access to medication abortion. A 2014 practice bulletin from the American College of Obstetricians and Gynecologists stated that telemedicine can be used to provide the procedure safely and effectively with a high level of patient satisfaction.

Although online options may offer either information or medications, there is no site that offers both, respondents told researchers. The lack of trusted online options may lead women to delay care or look to ineffective or unsafe alternatives, scientists say.

"We know that medication abortion is extremely safe and effective when carried out with the correct doses of medications, clear instructions and information about what to expect, and a reliable source of support and aftercare," said **Abigail Aiken**, MD, MPH, PhD, an assistant professor of public affairs and a fellow of the Richter Chair in Global Health Policy at the LBJ School of Public Affairs at the University of Texas at Austin, in a press statement. "Unfortunately, most current online options leave these needs unmet."

Restrictions Lead to New Avenues

In 2000, the Food and Drug Administration (FDA) approved mifepristone for use in early nonsurgical abortion. Since that time, states have enacted various restrictions of its use. Although the World Health Organization and the National Abortion Federation recommend that midlevel providers, such as advanced practice nurses and physician assistants, can provide medication abortion safely, many states limit provision of the drug to physicians only.

In 2016, the FDA issued new labeling for mifepristone, which lowered the recommended dosage of the drug, extended the timeframe for when a woman can take the pill, and reduced the number of provider visits.

For some abortion providers, telemedicine has offered a chance to extend access to medication abortion. A 2014 practice bulletin from the American College of Obstetricians and Gynecologists stated that the procedure can be provided via telemedicine safely and effectively and with a high level of patient satisfaction.[2]

A recent study looked at patients from Planned Parenthood of the Heartland in Iowa who received a medication abortion either via telemedicine or in person from 2008 to 2015. Of the nearly 20,000 patients included in the study, just 49 complications were reported. Data indicate there was no difference in the complication rate between women who received in-person care and those who used telemedicine.[3]

Women who received abortion care via telemedicine received the same level of evaluation as those who received in-person care, including having an ultrasound, which is viewed remotely by the physician. Physician visits were held through secure videoconference, and medication was dispensed remotely following physician evaluation. Women returned to the clinic about one week later for confirmation of successful procedures.

According to the Guttmacher Institute, 19 states currently require the clinician to be physically present when providing a medication abortion. This restriction prohibits using telemedicine for medication abortion.

> "THESE FINDINGS ADD TO OUR PREVIOUS RESEARCH DEMONSTRATING THAT TELEMEDICINE MEDICATION ABORTION WAS JUST AS EFFECTIVE AS MEETING WITH THE PHYSICIAN IN PERSON."

"This study included a large number of patients, so we can definitively conclude that telemedicine provision of medication abortion is not associated with a higher risk of complications compared with in-person provision," notes study co-author **Daniel Grossman**, MD, director of Advancing New Standards in Reproductive Health at the University of California, San Francisco. "These findings add to our previous research demonstrating that telemedicine medication abortion was just as effective as meeting with the physician in person, and satisfaction was also high among the women studied."[4]

Research Focuses on Access

Scientists affiliated with Gynuity, a reproductive health research organization, are conducting the TelAbortion Study, which is designed to evaluate providing medical abortion via telemedicine to women who have difficulty accessing abortion clinics.

After participating in a consultation with an abortion provider by videoconference, qualifying participants receive the necessary abortion medicines by mail. Investigators are collecting information to understand how well this model works and whether patients are satisfied with receiving abortion care in this way.

The study now is open to women in Hawaii, Oregon, Washington, New York, and Maine, and organizers hope to expand its access to other states.

Planned Parenthood affiliates in 10 states currently offer telemedicine abortion. Telehealth services also are available at a Whole Woman's Health clinic in Illinois and at Maine Family Planning in Maine. ■

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Researchers Examine Postmenopausal Bleeding and Endometrial Cancer

Is targeting women who have postmenopausal bleeding for early detection of endometrial cancer a useful strategy? To inform clinical decision-making, investigators performed an analysis looking at the frequency of postmenopausal bleeding in endometrial cancers and the risk of endometrial cancer among women who have postmenopausal bleeding.[1]

Unlike most cancers, endometrial cancer incidence and mortality rates in the United States have increased during the past several years.[2] Fortunately, if detected early, endometrial cancer can be highly curable, says **Megan Clarke**, PhD, MHS, a postdoctoral fellow at the National Cancer Institute's Division of Cancer Epidemiology and Genetics and lead author of the analysis.

In the current paper, Clarke says researchers set out to answer two important questions:

- How common is postmenopausal bleeding among women with endometrial cancer, particularly in early-stage cancers that have a high likelihood of being cured?
- How common is endometrial cancer in women with postmenopausal bleeding?

"Our study is the first to systematically evaluate these questions and provides precise estimates for the relationship between postmenopausal bleeding and endometrial cancer," notes Clarke. "These estimates can be used to support risk-informed decision making in clinical management of women with postmenopausal bleeding."

Review the Findings

For the systematic review and meta-analysis, researchers looked at 41,000 women from 129 studies. The review identified 34,000 women with postmenopausal bleeding and more than 6,000 women with endometrial cancer. Outcomes were pooled for the frequency of postmenopausal bleeding among women with endometrial cancer and the risk of endometrial cancer in women with postmenopausal bleeding.

The findings suggest that nine of 10 women diagnosed with endometrial cancer will present with postmenopausal bleeding, notes Clarke. "Importantly, this includes cancers at early stages that have a high chance of cure," she states. "However, less than 10% of women with postmenopausal bleeding will be diagnosed with cancer."

Talk With Patients

What are the ramifications for clinical practice? Providers should inform their female patients that postmenopausal bleeding can be a symptom of endometrial cancer and that they should seek medical attention if they experience this symptom, notes Clarke. However, clinicians also need to emphasize that postmenopausal bleeding is associated with many benign conditions and fewer than one in 10 women with postmenopausal bleeding will be diagnosed with endometrial cancer, she states.

Vaginal bleeding is the leading symptom in more than 90% of

EXECUTIVE SUMMARY

To inform clinical decision-making, investigators performed an analysis looking at the frequency of postmenopausal bleeding in endometrial cancers and the risk of endometrial cancer among women who have postmenopausal bleeding.

- Postmenopausal bleeding can be a symptom of endometrial cancer. However, it also is associated with many benign conditions. Fewer than one in 10 women with postmenopausal bleeding will be diagnosed with endometrial cancer.
- Transvaginal ultrasonography is indicated for an initial evaluation of postmenopausal bleeding if ultrasound images indicate a thin endometrial echo of 4 mm or less.

postmenopausal women who have endometrial carcinoma.[3] The risk factors include age, obesity, unopposed estrogen use, and comorbidities such as polycystic ovary syndrome, type 2 diabetes mellitus, or the presence of atypical glandular cells in screening cervical cytology. Clinicians should consider a family history of gynecologic malignancy when evaluating postmenopausal bleeding.

The American College of Obstetricians and Gynecologists issued a committee opinion in early 2018 on the use of transvaginal ultrasonography to evaluate the endometrium in women who have postmenopausal bleeding.[4] The opinion advises that transvaginal ultrasonography is indicated for an initial evaluation of postmenopausal bleeding if the ultrasound images indicate a thin endometrial echo of 4 mm or less. Transvaginal ultrasonography can be used as an alternative to endometrial sampling as an initial approach for postmenopausal women who have a first bleeding episode. If blind sampling does not detect endometrial hyperplasia or malignancy, then additional evaluation using hysteroscopy with dilation and curettage may be the most effective approach in evaluating women with bleeding that is persistent or recurrent. Use of transvaginal ultrasonography is not appropriate for screening postmenopausal women without bleeding for endometrial cancer, the opinion states.[4]

PROVIDERS SHOULD INFORM THEIR FEMALE PATIENTS THAT POSTMENOPAUSAL BLEEDING CAN BE A SYMPTOM OF ENDOMETRIAL CANCER AND THAT THEY SHOULD SEEK MEDICAL ATTENTION IF THEY EXPERIENCE THIS SYMPTOM.

How can women lower their risk of endometrial cancer? Achieving and maintaining a healthy weight is one approach. According to the American Cancer Society, women who are overweight or obese have up to three and half times the risk for the disease, compared with women who are at a healthy weight. Research also indicates that increasing physical activity may help lower endometrial cancer risk.[5] ■

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Gynecologic Cancers Detected Earlier Because of Affordable Care Act

The diagnosis of gynecologic cancers in young women is occurring at earlier stages because of implementation of the Affordable Care Act (ACA), according to results of a recent analysis.[1]

The five main types of gynecologic cancer are cervical, ovarian, uterine, vaginal, and vulvar. According to the Centers for Disease Control and Prevention (CDC), about 89,000 women per year are diagnosed with a gynecologic cancer. More than 29,000 per year will die from the disease, the CDC estimates.[2] Each year, about 2,000 women younger than 26 years of age are diagnosed with a gynecologic cancer.[3]

To perform the current analysis, researchers looked at the National Cancer Database, which contains

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- The five main types of gynecologic cancer are cervical, ovarian, uterine, vaginal, and vulvar. According to the Centers for Disease Control and Prevention (CDC), about 89,000 women per year are diagnosed with a gynecologic cancer. More than 29,000 per year will die from the disease, the CDC estimates. About 2,000 women younger than 26 years of age are diagnosed with a gynecologic cancer each year.
- Finding and treating cancer at earlier stages saves lives and reduces healthcare costs.

about 70% of the new cancer diagnoses in the United States. The scientists assessed women 21-26 years of age compared to a group of women 27-35 years of age. Women included in the analysis received a gynecologic cancer diagnosis between 2004 and 2009, before the legislation took effect, or between 2011 and 2014, after the healthcare law was implemented.

The researchers also reviewed how insurance coverage was associated with the stage of cancer diagnosis and receipt of treatment that protected fertility. Investigators adjusted for factors that may affect healthcare access, such as race, household income, and education level.

Researchers identified about 1,900 gynecologic cancers in women ages 21-26 prior to the ACA, compared to 2,059 in women following ACA implementation. In women ages 27-35, 9,782 cases were logged prior to the ACA, with 10,456 cases counted following implementation. When numbers were adjusted for factors such as education and income, data indicate that rates of those without insurance decreased and the diagnosis of cancer at early stages in younger women increased.

Prior to the law, 56.2% of women ages 21-26 were diagnosed with cancer at an early stage, compared to 61.2% following the law's implementation. Early-stage diagnosis did not change significantly in the comparison group, the researchers noted. For women in both age groups, the use of treatments that spare fertility increased: from 38.2% to 43.2% in young women, and from 17.6% to 20.6% in the comparison group.[1]

"We were pleased to see that there was a significant improvement in capturing more women's cancers early," says **Amanda Fader**, MD, associate professor of gynecology and obstetrics at the Johns Hopkins University School of Medicine and a senior author of the new study. "It can take decades to observe changes in population-based health trends, so to see differences this soon is promising."

"We know if these women are identified early and treated early, they are much more likely to live longer and have their cancer go into remission," noted **Anna Jo Bodurtha Smith**, MD, MPH, a resident in gynecology and obstetrics at the Johns Hopkins University School of Medicine and first author of the paper.

Earlier Diagnoses Are Key

Estimates indicate that implementation of the ACA led to an increase in health insurance premiums of 2.5% to 2.8%.[4] However, the cost to the U.S. economy for early deaths from gynecologic cancer is more than $2 billion per year.[1]

The costs of treatment for gynecologic cancers vary: for cervical cancer, the leading gynecologic cancer in young women, costs range from $25,000 to more than $500,000, with costs escalating for the required surgery, chemotherapy, and radiotherapy to treat advanced cases of the disease.[5] Finding and treating cancer at an early stage saves lives and reduces healthcare costs, says Fader.

"Survival rates improve dramatically when precancer or cancer is identified when the disease is confined to the organ of origin," noted Fader in a statement. "The cancer is much more likely to be treated successfully, and in the case of reproductive cancers, the potential to preserve fertility and the option of having children can be realized for more women."

Clinicians should talk with women about symptoms of gynecologic cancer, which can vary among women and by type of disease. Abnormal vaginal bleeding or discharge is common for all types of gynecologic cancers except vulvar cancer, while feeling full too quickly, having difficulty eating, or feeling bloated are common only for ovarian cancer.

Women with ovarian or uterine cancer often experience pelvic pain or pressure, while the need to urinate frequently or urgently and/or constipation are common for cancer of the ovary or vagina. Vulvar cancer involves symptoms such as pain, tenderness, itching, or burning of the vulva, and changes in the color or skin of the vulva, such as a rash, sores, or warts.[2] ■

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New Recommendations Focus on HIV Antiretrovirals

Clinicians involved in preventing and treating HIV will want to update their knowledge base with recommendations from the International Antiviral Society–USA for the use of antiretroviral drugs.[1]

The updated recommendations, issued by a volunteer panel of HIV research and patient care experts, offer guidance on the use of antiretroviral drugs, including how to initiate therapy, monitor individuals starting regimens, and how to change drug treatment. Information also includes how to prevent HIV infection in individuals at risk.

The new recommendations, which update information issued since 2016, reflect the joint commitment of researchers who are working together to improve clinical outcomes and treatments, says **Michael Saag**, MD, a professor of medicine at the University of Alabama at Birmingham's Division of Infectious Diseases and director of the university's Center for AIDS Research. Saag served as lead author of the current guidance.

"We know that antiretroviral therapy is the cornerstone of prevention and management of HIV infection, but it's critical to continually evaluate new data and treatments for initiating therapy, monitoring individuals starting therapy, changing regimens and preventing HIV infection for those at risk, reaffirming the standard of providing the utmost treatment and care possible," said Saag in a press statement.

What Are the Highlights?

Much has changed in the HIV prevention and treatment world since the society issued its first guidance in 1996. Highlights of the current recommendation include:

• Clinicians should update initial regimens, focusing primarily on unboosted integrase strand transfer inhibitor regimens. Rapid initiation of antiretroviral therapy is encouraged, including same-day initiation if possible.

• Routine use of *Mycobacterium avium* complex prophylaxis for those with advanced disease for antiretroviral therapy who are on effective therapy is not recommended.

• Discontinue use of routine CD4 count lab testing once a patient has sustained undetectable HIV RNA levels for a year and has a CD4 count above 250 cells/µl.

• One option for preexposure prophylaxis for those who are uninfected with HIV but remain at risk for infection is to include an episode-based approach, whereby patients can take preventive antiretroviral pills prior to exposure, with a follow-up pill once daily for two days post-exposure.[1]

"HIV care continues to evolve, and clinicians and their patients benefit

EXECUTIVE SUMMARY

Clinicians involved in preventing and treating HIV will want to update their knowledge base with recommendations from the International Antiviral Society–USA for the use of antiretroviral drugs.

- The updated recommendations, issued by a volunteer panel of HIV research and patient care experts, offer guidance on the use of antiretroviral drugs, including how to initiate therapy, monitor individuals starting regimens, and how to change drug treatment. Information includes how to prevent HIV infection in individuals at risk.
- While researchers continue to search for a cure, scientists also are looking to achieve sustained, antiretroviral drug therapy-free remission of HIV.

from applying the latest knowledge to keep pace with the many ways this has changed," said study co-author **Paul Volberding**, MD, a professor at the University of California San Francisco. "The latest IAS-USA guidelines continue a tradition of providing a concise and current set of recommendations, and we are proud of how these have captured the directions in our field of medicine."

A multipronged approach is necessary to address the HIV epidemic effectively, noted **James Riddell**, IV, MD, a professor of internal medicine at the University of Michigan, in an accompanying commentary. These approaches should include HIV preexposure prophylaxis, condom use education, expanded testing for HIV, rapid and immediate linkage to care, achievement of viral suppression in those infected with the disease, and ways to improve therapy compliance and continuation of care.[2]

Future Advancements Await

While researchers continue to search for an HIV cure, scientists also are looking to achieve sustained antiretroviral drug therapy-free remission. In this approach, the objective is not to eradicate all of the virus-carrying cells in the body, which are known as the HIV reservoirs. Rather, sustained remission would allow a person living with HIV to maintain suppression of the latent virus without using daily medication.

One scientific approach in remission therapy relies on intermittent or continual non-antiretroviral drug interventions. Another method involves stimulating the immune system to independently have long-lasting control over HIV. Broadly neutralizing HIV antibodies now in research are offering potential solutions for intermittent or continual interventions for long-lasting remission free from antiretroviral therapy.[3,4] Research in animals and humans is ongoing to find out if periodically receiving infusions or injections of such antibodies can prevent someone from acquiring the virus, as well as suppress it in people who are living with the disease.

In another approach, researchers are analyzing broadly neutralizing HIV antibodies in stimulating the immune system. In early research, scientists at the National Institute of Allergy and Infectious Diseases and Rockefeller University demonstrated that when monkeys infected with a simian form of HIV received infusions of two different types of antibodies, the immune systems of some of the animals were able to control the virus long after the antibodies had dissipated.[5] ■

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COMING IN FUTURE MONTHS

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- New drug targets identified in fight against HIV

CONTRACEPTIVE TECHNOLOGY UPDATE®

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CME/CE QUESTIONS

1. What are the active ingredients in the Annovera contraceptive vaginal ring?

a. Segesterone acetate and ethinyl estradiol
b. Desogestrel and ethinyl estradiol
c. Segesterone acetate and mestranol
d. Norgestrel and ethinyl estradiol

2. When is transvaginal ultrasonography indicated for an initial evaluation of postmenopausal bleeding?

a. When ultrasound images show a thin endometrial echo of 2 mm or less
b. When ultrasound images show a thin endometrial echo of 3 mm or less
c. When ultrasound images show a thin endometrial echo of 4 mm or less
d. When ultrasound images show a thin endometrial echo of 5 mm or less

3. What were the changes in the 2016 labeling for mifepristone issued by the Food and Drug Administration?

a. Increased recommended dosage; extended timeframe for taking the pill; reduced number of provider visits
b. Decreased recommended dosage; extended timeframe for taking the pill; reduced number of provider visits
c. Decreased recommended dosage; decreased timeframe for taking the pill; reduced number of provider visits
d. Decreased recommended dosage; decreased timeframe for taking the pill; increased number of provider visits

CME/CE OBJECTIVES

After reading *Contraceptive Technology Update*, the participant will be able to:

1. identify clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services;
2. describe how those issues affect services and patient care;
3. integrate practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts;
4. provide practical information that is evidence-based to help clinicians deliver contraceptives sensitively and effectively.